

### **Remarks**

The Office Action dated May 12, 2005, has been carefully reviewed and the following comments are made in response thereto. In view of the following remarks, Applicants respectfully request reconsideration and reexamination of this application and the timely allowance of the pending claims.

The amendments to the claims (including claim cancellation) presented herein are made without acquiescing to the merits of the rejection and solely for the purpose of advancing prosecution. Amendments are also made without prejudice to Applicants' right to file a divisional or continuation application directed to any of this subject matter.

While written support for the claims amendments can be found throughout the specification, specific written support can be found as set out below. Applicants therefore submit that no new subject matter has been added by the amendments to the claims and that they are fully supported by the text of the specification.

All independent claims are now directed to an alfalfa variety, which finds support in the application as filed at page 1, line 14. Claims 32 and 33 refer to leaf tannins, which finds support in Tables 4 and 5 (these tables report scores for leaf tannins) and in original claim 2.

Claim 32 requires that the percentage of plants of said variety scoring 3.0 or higher for leaf tannins using the DMACA-HCL protocol is at least 25%. This finds support at page 25 lines 14-15 and in Table 4. The conditions are field conditions with day temperatures reaching from about 90 to about 100 degrees F and night temperatures between about 60 to about 70 degrees F, which finds support at page 25, line 26 and page 26, lines 7-9.

Claim 33 requires that the claimed variety is produced by selection for improved leaf tannins when grown in conditions selected from field and greenhouse conditions, said selection comprising a selection intensity of at least about 15% over at least one generation. This finds basis at page 5, lines 13-17 and at page 13, lines 19-25. Selection of conditions from field and greenhouse conditions finds support in Tables 4 and 5.

Claim 34 states that the variety has sufficient tannins when field or greenhouse grown to confer improved bloat safety to the variety when used as forage as compared to the Weston variety. This claim corresponds to claim 30 as originally filed. The feature that improved bloat

safely is conferred by tannins finds support throughout the application as filed, *inter alia* at page 3, line 29 to page 4, line 2; page 4, line 28 to page 5, line 2; and page 5, lines 10 to 12. Use of the variety as a forage is implied by the property of improved bloat stability and finds further support at page 5, line 26. Comparison to Weston as a reference variety finds basis at page 25, lines 27 to 29. Selection of conditions from field and greenhouse conditions finds support in Tables 4 and 5.

Claims 35 and 36 correspond to claims 17 and 18 of the application as filed.

### **Response to the Office Action**

Before addressing the Examiner's specific objections/rejections, Applicants believe that it would be helpful to briefly summarize the nature of the present invention and its relation to the prior art.

Prior to the present invention, there was no recognition that alfalfa plants (rather than alfalfa seeds) contained tannins. This is explained in the present application at page 4, lines 21 to 26, which states that it has long been held that alfalfa herbage does not contain measurable levels of tannins. Indeed, Coulman *et al.* (2000) conclude that it was not possible to produce a leaf-tannin containing alfalfa by conventional breeding techniques. Nor had experiments using tissue culture methods reported any success in producing plants with leaf tannins outside of the culture conditions (Lees, 1992). Success outside of culture conditions is required to achieve an improved commercial plant, to be used as animal forage.

Thus, prior to the present invention, the prevailing opinion in the art was that alfalfa did not have tannins in its leaves, at least when grown outside of culture conditions. In view of this, the skilled person could not undertake any procedures to improve leaf tannin levels in the crop—no suitable starting material for such procedures was considered to be available.

Surprisingly, and contrary to the prevailing opinion at the time, the present inventors screened a number of alfalfa plants using the DMACA-HCL protocol, and found that using this protocol, about 50% of plants chosen to be used in the studies showed at least some level of leaf tannin (see Example 1 of the present application). The level of tannin within this 50% varied, with some plants scoring only 1.0 on the scale, and some scoring up to 5.0.

This recognition, made for the first time by the present inventors, allows the person of ordinary skill in the art to select the higher-tannin plants for use in a breeding program or for use in isolation of genes responsible for tannin production, and to develop an improved variety.

Applicant turns now to addressing the Examiner's specific comments. Comments are made using the section numbering of the office action.

4. The Examiner has objected to claim 5 for allegedly failing to further limit the subject matter of a previous claim. Claim 5 has been cancelled in the present response and hence this objection is moot.

5. The Examiner has objected to previous claims 17 and 19 for the word "seed", as the claims allegedly do not read onto a single invention.

Previous claims 17 and 19 have been cancelled. Claim 36 refers to seed of an alfalfa variety defined according to preceding claims 32, 33 or 34. It is submitted that this refers to a single invention, namely, the seed population which would give rise to a variety as claimed. Thus, it is submitted that this objection is not applicable to present claim 36.

6. The Examiner has objected to the phrase "alfalfa plants" in previous claim 30. Previous claim 30 has been cancelled and hence this objection is moot.

7. An Information Disclosure Statement is filed herewith, containing documents filed with the third party observations.

8-9. The Examiner has rejected claim 4 under 35 U.S.C. §112, second paragraph, because the term "higher than that found naturally" is allegedly a relative term which renders the claim indefinite.

Claim 4 has been cancelled in the present response.

It is noted that present claim 34 explicitly refers to the commercially available Weston variety as a standard for the improved bloat safety and thus the person of ordinary skill in the art is fully apprised of the scope of the invention.

10. The Examiner has rejected claims 1 to 21 and 30 under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the written description requirement. The Examiner states that claims 1 to 21 are “broadly drawn to any alfalfa plant with detectable levels of tannins and the seed and pollen of said plant”. The Examiner further states that the specification does not provide a written description of the genus of alfalfa plants with regards to their genetic, morphological and/or physiological characteristics, and that only two species are described in the specification.

Claims 1 to 21 and 30 have been cancelled in the present response and so the rejection is moot.

In respect of the new claims, it is noted that as explained above, the present application allows the skilled person for the first time to produce an alfalfa variety having improved tannins, by virtue of identifying that a significant percentage of alfalfa plants have leaf tannins, showing that some alfalfa plants have higher leaf tannins than others, and allowing the person of ordinary skill in the art to identify the higher-tannin plants. The applicability of this invention is not limited to particular starting populations, and hence different varieties can be produced using the teaching of the invention. The person of ordinary skill in the art would recognize that the invention is operable in respect of a wide range of other species, in addition to the ones disclosed. Thus, the disclosed species are representative of the genus, and the ordinary skilled person would recognize that the inventors had possession of the claimed invention at the time of filing. Furthermore, the Examiner is incorrect in stating that only two species, namely CW 28061 and CW 29052, are described in the specification. The Examiner may have chosen to list only these two varieties since they are the only ones specifically claimed in the originally-filed claims. However, the specification provides other representative examples of alfalfa varieties that meet the requirements of the presently-pending claims. See, for example, alfalfa varieties CW 29053 and CW 09052 in Table 5.

The Examiner also states that claim 30 is broadly drawn to any alfalfa plant with improved bloat safety and that the specification does not provide a written description of any alfalfa plant with improved bloat safety in terms of its genetic, morphological and/or physiological characteristics.

Present claim 34 states that the improved bloat safety is conferred by the plant tannins.

Thus, the relevant physiological characteristic of the plant is described in the specification (namely, increased tannins in the plant). The person of ordinary skill in the art would be aware of the importance of tannins in improving the bloat safety of plants. It is further noted that the tannin content is a structural feature which is suitable to distinguish from other materials.

For each of the above-stated reasons, it is submitted that claims 32 to 36 meet the requirements of written description under 35 U.S.C. §112, first paragraph.

12. The Examiner has rejected previous claim 16 under 35 U.S.C. §112, first paragraph, for allegedly failing to comply with the enablement requirement, because the parent plants of Table 3 are allegedly essential to the claimed invention and it is not apparent if the plants are readily available to the public. This claim has been cancelled and so this rejection is now moot.

13. The Examiner has rejected previous claims 1 to 21 and 30 under 35 U.S.C. §112, first paragraph, as failing to comply with the enablement requirement, as the claims allegedly contain subject matter which was not described in the specification in such a way as to enable one of skill in the art to make and/or use in the invention.

The Examiner has stated that:

- the skilled person would not know how to distinguish the claimed alfalfa plants from any other alfalfa plant;
- there is no evidence that any of the listed parent plants in Table 3 have been used to produce an alfalfa plant with detectable levels of tannins and thus it would require undue experimentation for one skilled in the art to screen all of the listed parents to determine which, if any, would produce an alfalfa plant with detectable levels of tannins;
- alfalfa species differ in their genetic/morphological and physiological backgrounds and so it would require undue experimentation to select all possible alfalfa plants to determine which, if any, would have detectable levels of tannins

as well as cross all possible alfalfa plants, if possible, to produce an alfalfa plant that would have detectable levels of tannins;

- Claim 30 is broadly drawn to any alfalfa plant with improved bloat safety and the specification does not teach how to make and use any alfalfa plant with improved bloat safety; and
- Selecting alfalfa plants for detectable tannin levels is not predictable.

Claims 1-21 and 30 have been cancelled herewith, and so the rejection is moot.

In respect of the new claims, it is noted that as explained in detail above, the present inventors recognized for the first time that in populations of alfalfa, at least some plants have leaf tannin, and that the levels of leaf tannin in those plants which express it is variable. This allows the person of ordinary skill in the art to produce a variety having increased tannins in the plant, by selecting those plants in the population which have the higher levels of tannin as parents, e.g., as parents for use in developing a synthetic variety. The application as filed provides evidence that the tannin expression is heritable, since varieties were developed by conventional breeding combined with selection for tannins. Thus, having identified those plants with higher tannins levels, conventional breeding techniques can be applied to produce new varieties with improved tannins using methods that would be conventional to one of ordinary skill in the art. These can then be used to provide forage/feed with improved bloat safety as described in the specification. Thus, the present specification teaches the skilled person how to make and use the invention across the scope of the claim.

With regard to the Examiner's comment that there is no evidence that any of the listed parents in Table 3 have been used to produce an alfalfa plant with detectable levels of tannins, the specification describes that Table 3 summarizes the plants in the different crossing groups that resulted in cycle 1 seed. Each of the crossing groups summarized in Table 3 was used to produce a cycle 1 variety, wherein the percentage of plants in the cycle 1 variety had significantly increased, from about 15% to about 25% (page 25, lines 14-15). Thus, the application as filed described multiple crossing groups, all of which resulted in a variety showing improved plant (*i.e.*, leaf) tannin.

The Examiner has further stated that selecting plants for a detectable level of tannins is not predictable, because the specification teaches that temperature can play a role in the detection of tannin levels in alfalfa and also the age of the leaf may make it difficult to determine if a plant has detectable levels of tannins. However, it is respectfully submitted that by pointing out the effect of temperature and leaf maturity, the teaching of the application allows the person skilled in the art to avoid any difficulties that these factors may cause.

The present inventors were able to consistently select for improved average tannin content in a number of different crossing groups, as explained above, thus demonstrating that selection is in fact sufficiently predictable.

The Examiner has also stated that Bula *et al.* (Crop Sci. 14:618-621, 1974) teach that repeated sexual prorogation of an alfalfa synthetic may lead to changes in cultivar characteristics such that the subsequent generations would no longer be similar to the original release. However, this is referring to multiplication of a variety once established and not to propagation with selection for the desired characteristic. Thus, this document is clearly not relevant to the present invention.

Moreover, it is noted that Bula *et al.* teach that “changes in cultivar characteristics can be reduced to a point where they are of no practical significance if appropriate precautions are used during seed multiplication (2, 5)” (paragraph spanning pages 618 and 619). Thus, the person of ordinary skill in the art would be able to undertake multiplication as needed while maintaining characteristics using routine methods known in the art as taught by the reference relied upon by the Examiner.

Finally, it is noted that new claim 34 requires that the improved bloat safety is conferred by the plant tannins, and thus the physiological characteristics leading to the improved bloat stability are identified in the claim.

It is therefore submitted that all of the present claims comply with the enablement requirement of 35 U.S.C. §112, first paragraph.

15. The Examiner has rejected claims 1 and 4 to 21 under 35 U.S.C. 102(b) as being allegedly anticipated by Goplen *et al.* (1980), which refers to alfalfa plants with detectable tannins in seeds.

Claims 32 and 33 state that the tannin is leaf tannin. Claim 34 states that the variety shows improved bloat safety when used as forage. Thus, the relevant tannin levels are in the plant and not the seed.

Moreover, in the absence of detection of tannins in the plant itself in the prior art, the skilled person has no means to obtain any plant variety showing improved plant tannin content. For example, in Goplen *et al.* it is stated that:

“No tannins were found in any of the 1,000’s of accessions, varieties, or breeding populations of alfalfa. Similarly, no tannin-containing plants were found in 20,000 plants of 4n *M. sativa* alfalfa, nor 6,000 plants of 2n *M. falcata* alfalfa following treatment with chemical mutagens”. (Page 802, left hand column, last paragraph).

In view of the scale of the screening program and its lack of success, the authors conclude that screening for an alfalfa plant containing leaf tannin would be futile – “the routine screening of large alfalfa populations in this study and that of Rumbaugh (1979) indicate the futility of this approach” (page 803, right hand column). Thus, Goplen *et al.* does not teach any method of obtaining alfalfa plants having improved tannins, nor any varieties having the features of the present claims. The claims are therefore novel over this document. Certainly, this document cannot render the present claims obvious either since it teaches strongly against even attempting the very invention of the present claims.

16. The Examiner has rejected claims 2-3 under U.S.C. 102(b) as allegedly being anticipated by Lees (Plant Polyphenols, pp. 915-934, 1992). The Examiner states that Lees discloses alfalfa plants having levels of tannin in their leaves while in tissue culture.

All independent claims now state growing conditions, which are either field conditions (claim 32) or selected from the group consisting of field and greenhouse conditions (claim 33 and 34). Lees (1992) does not teach plants having improved tannin content outside of tissue culture conditions. Thus, all claims are novel over Lees (1992).

17. The Examiner has rejected claim 30 under 35 U.S.C. 102(b) as being anticipated by Coulman *et al.* (Can. J. Plant Sci. 80(3): 487-491, 2000). The Examiner states that Coulman *et al.* discloses a bloat reduced alfalfa cultivar.



Coulman *et al.* uses selection for low rate of initial digestion as a way of trying to improve bloat safety. The rate of initial digestion is a different causal factor contributing to bloat than a lack of condensed tannins, as set out in the abstract of the paper. Coulman *et al.* does not show any development of an alfalfa variety with improved tannin levels, and thus claim 34 is novel over this document.

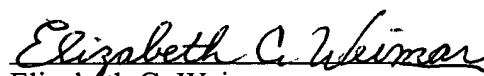
### **Conclusion**

Applicants respectfully request reconsideration of the subject application in view of the above remarks and withdrawal of the rejections. It is respectfully submitted that this application is now in condition for allowance. Should the Examiner believe it to be useful, an interview with the Examiner is respectfully requested in order to discuss the foregoing claims.

If there are any fees due in connection with the filing of this amendment, please charge the fees to our Deposit Account No. 50-310. If a fee is required for an extension of time under 37 C.F.R. 1.136 not accounted for above, such an extension is requested and the fee should also be charged to our Deposit Account.

Respectfully submitted,

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